MASTER OF SCIENCE PROGRAM IN

CLINICAL AND POPULATION TRANSLATIONAL SCIENCE

THE DIVISION OF PUBLIC HEALTH SCIENCES

WAKE FOREST UNIVERSITY
GRADUATE SCHOOL OF ARTS & SCIENCES
BOWMAN GRAY CAMPUS

PROGRAM HANDBOOK

August 2016

If you have further questions after reading this handbook, please contact the Program at cpts@wakehealth.edu.
BACKGROUND AND PHILOSOPHY

For over two decades, the Division of Public Health Sciences has provided training in clinical research. To reflect an emphasis on translational research, the Master of Science degree in Clinical and Population Translational Science (CPTS) was initiated in the fall of 2008. This Program is among a small number of similarly structured graduate programs in the United States, placing it on the cutting edge of graduate education.

Major changes have occurred in basic, clinical and population-based research in the last several years. In the past, basic, clinical and population-based researchers operated in separate domains, often without substantive interactions. This model of research has created barriers to translating research into practice. At present, and increasingly in the future, it will be necessary for scientists to be able to collaborate effectively across the research spectrum to accelerate the translation of knowledge into improvements in human health.

Within the field of clinical research, morbidity and mortality have been the primary outcomes assessed to evaluate treatment effectiveness. However, patient and provider satisfaction, health-related quality of life, health care expenditures, and cost-effectiveness are now evaluated with great regularity. This shift in emphasis is being driven, in part, by the changing health care system, which is demanding more complete information on physician practice patterns, clinical/patient outcomes, and the cost-effectiveness of therapies across a wide range of medical conditions. In addition, health outcomes and services are becoming more central to the funding structures of health care research. For example, the National Cancer Institute strongly encourages the inclusion of health-related quality of life and economic impact measures in clinical trials. These factors are also becoming more central in the drug approval process, making the assessment of these outcomes more critical in the pharmaceutical industry.

In response to these changes, academic medical centers are redesigning their clinical delivery systems to conform to a system configured around capitated payment and fixed populations of patients in defined communities. Physicians and other health care professionals are also being asked to assume roles quite different from the traditional roles for which they were trained. Among these new roles are the responsibility for the delivery of cost-effective health care and preventive services to communities; the allocation of scarce health care resources; and the assessment of medical treatment effectiveness, including the evaluation of patient outcomes such as health-related quality of life. Academic research in health care also requires a broader combination of skills to more effectively examine the etiology, detection, prevention, and treatment of disease, in order to better inform the health care delivery system. Increasingly, multidisciplinary teams of researchers are required to address the complex research questions of importance in clinical research.
Within the field of population-based research, the linkages between public health and medical approaches to improving health are increasingly recognized. The Medicine and Public Health Initiative, an alliance of the American Public Health Association and the American Medical Association, has focused on engaging leading medicine and public health organizations and individuals in efforts to reshape health education, research and practice. This includes a focus on putting evidence-based results into practice through applied and translational research. The clinical and population translational scientists of tomorrow must be prepared to conduct the research needed to advance methods for putting results we know into practice; to help determine gaps in coverage or in emphasis; to help assess ethical aspects of this research; to contribute to the determination of the long term cost-effectiveness of specific lines of research; to help develop public policy regarding areas of research development and implementation; and to help members of all health professions to become aware of and to utilize the most important research conclusions as they appear.

The combination of epidemiology; statistics; and clinical and population research methods into one program will provide students with the skills necessary to translate discoveries generated during laboratory research to human populations and to conduct research aimed at enhancing the adoption of best practices in health care settings and the community. Students also will be prepared to function in multidisciplinary teams that will conduct the translational research of the future.

PROGRAM OVERVIEW

The Master of Science (MS) Degree in CPTS is administered by the Division of Public Health Sciences. Faculty members provide expertise and conduct research across the spectrum of basic, clinical, population, and translational research. The Program is managed by two Program Directors and a Program Coordinator. Unless otherwise noted, the Program follows the policies and procedures of the Wake Forest University Graduate School of Arts and Sciences (Bowman Gray Campus).

Formal coursework for the CPTS Program emphasizes biostatistics, epidemiology, and applied clinical and population research methods, along with the responsible conduct of research and scientific communication. Competencies addressed by the formal CPTS coursework include the ability to:

- Develop meaningful and feasible research questions based on literature review and appropriate biological and psychosocial conceptual frameworks.

- Design and implement studies to answer research questions, with appropriate balancing of competing considerations involved in decisions about study design; participant sampling and recruitment; and approaches to data collection.

- Perform and interpret statistical analyses based on a foundation of statistical literacy, with graduates able to perform basic analyses on their own and
prepared to collaborate with statisticians for more complex analyses.

- Conduct research in a responsible and ethical manner.
- Communicate scientific concepts orally and in writing, including through grant applications, protocols, manuscripts, abstracts, and presentations.
- Collaborate productively in the context of multidisciplinary scientific teams comprised of basic, clinical, and population scientists.

The course sequence and descriptions are provided below. In addition to formal coursework, all students pursuing a Master’s degree in CPTS are required to complete a thesis of publishable quality that is closely aligned with the student’s interests and career objectives. The thesis provides a capstone experience in which students apply the knowledge and skills obtained during their formal coursework. Further information about thesis requirements is provided in several following sections.

Students pursuing a medical or physician assistants (PA) degree at the Wake Forest School of Medicine can incorporate the CPTS MS into their medical training, ideally between the second and third years for medical students and the first and second years for PA students.

CPTS CERTIFICATE PROGRAM

An abbreviated program resulting in the granting of a Certificate rather than an MS may be suitable for students who do not have time to go through the full MS program of study and the completion of a thesis. The purpose and entrance requirements are identical to the MS program. Students will need to complete at least 15 hours of CPTS coursework, complete ethics training requirements, and demonstrate competency in basic biostatistics. At least 10 hours of coursework is required from these core classes: CPTS 720, CPTS 741, CPTS 742, CPTS 748, CPTS 749. All students are required to take the CPTS ethics sequence (CPTS 703 and 704). Participants must enroll in one of the CPTS statistics courses, CPTS 730 or 732, or have the biostatistics requirement waived by the program directors by demonstrating at least 4 credit hours of graduate biostatistics with a grade of B or better in a course deemed to be comparable to CPTS 730. CPTS 732 requires CPTS 730 as a pre-requisite or permission of the instructor.

ADMISSION STANDARDS AND PROCEDURES

The CPTS Program is open to individuals who already hold or are pursing advanced degrees, such as the MD, DVM, ScD, PhD, DDS, DSN, MMS, or MSN, who are seeking training in the clinical and population aspects of translational research. The Program also may be appropriate for qualified applicants with at least a BA or BS in a social science, public health, or other health-related field, although additional post-baccalaureate course work is highly desirable. For applicants without an advanced
degree, extensive previous experience in a health-related field is required. All applicants must provide GRE, MCAT, or USMLE scores, to be forwarded by the testing institution directly to the Dean of the Graduate School.

Application decisions are made on a rolling basis beginning on January 15, the application deadline for the Graduate School. Available slots in the Program are typically filled by early May. New applications will not be accepted after the Program is filled. In addition to the required written application materials, applicants typically are interviewed by phone. Upon admission, all students must matriculate at the beginning of the subsequent fall semester; matriculation in the spring or summer semesters is not possible. Applications must be filed electronically through the Graduate School (http://graduate.wfu.edu/admissions/onlineapp.html).

PARTICIPATION BY STUDENTS NOT ENROLLED IN THE CPTS PROGRAM

Students who wish to audit or take a course for credit in the CPTS Program must either be enrolled in another WFU Graduate Program or receive special student status from the Graduate School. Obtaining special student status typically requires provision of transcript(s) and proof of required vaccinations. Students must meet course prerequisites and receive permission of the instructor (POI) to register. When CPTS courses are oversubscribed, priority will be given to full-time students whose program requires the course; auditors will be the lowest priority. Auditors attend lectures but should not expect to participate fully in course activities or have assignments evaluated.

FINANCIAL CONSIDERATIONS

The Graduate School sets tuition and fees, and provides information regarding financial aid. Tuition and fees are the responsibility of the student, although they may be funded in part by training programs or Medical School departments.

In order to access course materials, CPTS students must have ongoing access to a computer with internet access that meets the security requirements of the Wake Forest School of Medicine. A laptop with wireless capacity is preferred given the ability to access the internet and complete statistical analyses and other activities during class sessions. Students are required to have access to SAS. Access is currently available through the Division of Public Health Sciences license, although this is subject to change. Division staff will be available to install the software but cannot provide any additional technical support. Information on obtaining your own license through the SAS program is available at http://support.sas.com/learn/ap/student/index.html.

All students are responsible for covering their living expenses through employment, formal training programs, financial aid, or other means. This includes required health insurance. A common health insurance plan and support toward its premium will be provided by the Graduate School for students who do not have access to insurance.
Students also may be asked to undergo a physical examination at Employee Health and submit required documentation.

INTERNATIONAL STUDENTS

Applications from international students are accepted. Admitted students are responsible for obtaining the necessary visas and following all other regulations and policies. Students also must demonstrate that they have sufficient funds to support themselves while in the United States. Assistance with visa issues can be obtained from the Admissions Coordinator of the Graduate School, Bowman Gray Campus (Ms. Elizabeth Whitsett (bwhitset@wakehealth.edu). The WFU Center for International Studies provides information about regulations, housing, and local services; please see http://global.wfu.edu/iss/.

PROGRAM REQUIREMENTS AND RELATED INFORMATION

All prospective students should consult the Bulletin of the Wake Forest University Graduate School for official policies and procedures of the Graduate School, available at http://graduate.wfu.edu/bulletin.html. The following degree requirements pertain specifically to the CPTS Graduate Program. Please note there is no certificate option in the CPTS Program.

MS TIME TO COMPLETION

Obtaining the MS typically requires a minimum of two full-time years (one each for coursework and thesis preparation); the expected time to completion for full-time students is two years. Part-time status to extend coursework over more than one year requires the prior approval of the CPTS Program Directors. The degree should be completed within one to two years from the completion of coursework, with the possibility of a maximum of two one-year extensions (see below for details). Coursework must include a minimum of 30 semester hours of graduate credit, with at least six hours of thesis research credits.

FACULTY ADVISING

Advising involves both the Program Directors and faculty advisors. During the first year of study, students will work with the Program Directors to identify a faculty advisor in the student’s area of interest. Ideally this advisor would also serve as the student’s thesis committee chair, so students and their faculty advisors are encouraged to meet occasionally during the coursework year. Program Directors are available to students and their advisors as needed.
COURSEWORK

The Graduate School determines the Academic Calendar, found at http://graduate.wfu.edu/bulletin.html. During fall and spring terms, students should plan to spend the entirety of each Tuesday and Thursday in class. The summer course meets on Tuesday and/or Thursday morning. Courses are held at the 525@Vine building in the Wake Forest Innovation Quarter. Nearby parking is available; details will be provided at the time of matriculation.

The course sequence for the first year of the CPTS program appears in the table below. Course registration is handled by the Graduate School.

CPTS Coursework

<table>
<thead>
<tr>
<th>Fall (11 hours)</th>
<th>Spring (12 hours)</th>
<th>Summer (6 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidemiology (CPTS 720, 4 hours)</td>
<td>Clinical Trial Methods (CPTS 742, 3 hours)</td>
<td>Research Grant Preparation (CPTS 741, 3 hours)</td>
</tr>
<tr>
<td>Introduction to Statistics (CPTS 730, 4 hours)</td>
<td>Applied Linear Models (CPTS 732, 4 hours)</td>
<td>Thesis Research (CPTS 750, 3 hours)</td>
</tr>
<tr>
<td>Population Methods I (CPTS 748, 2 hours)</td>
<td>Population Methods II (CPTS 749, 4 hours)</td>
<td></td>
</tr>
<tr>
<td>Ethics and Responsibility in CPTS I (CPTS 703, 1 hour)</td>
<td>Ethics and Responsibility in CPTS II (CPTS 704, 1 hour)</td>
<td></td>
</tr>
</tbody>
</table>

Students who wish to pursue individualized study in area of particular interest to them may arrange with a CPTS faculty member to do so for credit through an elective course.

A student may petition the Program Directors for exemption from a required course if a similar course has been completed in the past. The student must provide a syllabus from the course and the final grade must appear on a transcript submitted as part of the Graduate School application. Alternatively, the student may be allowed to prove competency in the subject matter by completing the final examination from the most recent semester. All requests will be reviewed on a case-by-case basis.

In addition to the required coursework, students are encouraged to attend and participate in seminars, journal clubs, and similar events sponsored by the Division of Public Health Sciences, Clinical and Translational Science Institute, their home department, and others. Such attendance typically does not receive academic credit, although attendance could be incorporated into a for-credit course of individual study arranged by the student with a CPTS faculty member.
PROGRESS IN COURSEWORK AND ADMISSION TO DEGREE CANDIDACY

Satisfactory progress in course work requires that students maintain a cumulative “B” average or higher, equal to or greater than a 3.0 on a 4.0 scale. Receipt of a course grade of “B-” or lower requires communication among the student, their advisor, and CPTS Program Co-Directors. Additional work may be required to meet competency requirements of the program. Transcripts are reviewed each semester by the Program Directors.

Students who experience a major life event that is likely to disrupt their progress toward a degree may request a one-year leave of absence. This year does not count toward any time limitations. Either the Graduate School Registrar or CPTS Program Directors can assist a student in requesting a leave. The Program requires the Graduate School leave policies, available at http://graduate.wfu.edu/students/leaveofabsence.html.

ADMISSION TO AND MAINTENANCE OF DEGREE CANDIDACY

After completing all required coursework, and prior to beginning their thesis, students must be admitted to degree candidacy by the Dean of the Graduate School. The application for candidacy is automatically submitted by the CPTS Program Directors and Coordinator after they receive the summer semester grade reports. This typically occurs in late August. Students do not need to initiate or participate in this process.

Upon admission to degree candidacy, students must be continuously enrolled until they graduate. In the second year of the program students will register for 9 hours of research with their advisor in the fall, 5 to 9 hours in the spring semester plus an additional 3 hours in the summer semester. Tuition is the responsibility of the student, although they may be funded in part by training programs and Medical School departments. Thesis-only status is restricted and requires the permission of the Graduate School.

THESIS COMMITTEE FORMATION AND FUNCTION

After being admitted to degree candidacy, a Thesis Committee must be formed to advise each student on their thesis. The student’s faculty advisor and the CPTS Program Directors will assist the student in identifying committee members and obtaining their commitment to serve. The Thesis Committee is made up of the faculty advisor, who will serve as the thesis committee chair, a statistician, and one to two other faculty members. For clinically trained students, the Committee would ideally include a faculty member with substantial research experience. For non-clinically trained students, the Committee would ideally include a faculty member with relevant clinical expertise.

Students should form a Thesis Committee as soon as possible after completing their second semester of coursework and well in advance of seeking approval of a thesis
proposal, and fill out the Approval of Thesis Committee form (see https://www.phs.wakehealth.edu/docs/cpts/APPROVAL%20OF%20THESIS%20COMMITTEE%20FORM.pdf). Thesis Committee members must be members of the Graduate School Faculty. Please note that members of the Medical School Faculty are not automatically members of the Graduate School Faculty. Arrangements for cross-appointments are straightforward but can take several weeks to process. The CPTS Program Coordinator will assist with these arrangements. Graduate Faculty are listed at http://graduate.wfu.edu/faculty/directory.html.

Students are required to notify the Graduate School and Program of their Committee’s membership using the “Statement of Intent to Receive a Graduate Degree” form available at http://graduate.wfu.edu/Forms/BG%20Campus/BG_stmtofintent.pdf.

In addition to meeting to approve the thesis proposal and again for the thesis defense, the student should meet regularly with the faculty advisor and as needed with other committee members to ensure the student makes steady progress toward thesis completion. The student, faculty advisor, or any committee member can initiate a request for a meeting if they feel there is a need to discuss issues in person. If the student, faculty advisor, or any committee member has questions or concerns about their role and responsibilities, or the function of the committee, they should contact one of the CPTS Program Directors.

THESIS TOPIC

An important goal of the CPTS Program is that thesis research serves directly to advance the scientific and professional careers of the students. Students should therefore choose a topic that will further their career objectives and be publishable in their major field of interest. The thesis topic may require primary data collection or rely on secondary data analysis from an ongoing or completed study or another source of existing data. The thesis topic must constitute a new piece of work for the student; work completed prior to enrollment is not acceptable. Students should work closely with their faculty advisors to select their thesis topic.

APPROACH TO AND FUNDING FOR THE THESIS

The thesis represents the culmination of the students’ graduate training and thus students are expected to complete their theses independently, albeit with the advice and support of their thesis committee. Students are responsible for all written drafts and revisions, and should complete their own statistical analyses. Advisors may provide substantial feedback and sample statistical programs but may not write portions of the thesis nor conduct analyses for the student.

Thesis preparation costs are the responsibility of the student and their department, training program, and thesis committee members’ intramural or extramural research support.
THESIS PROPOSAL AND APPROVAL

Each student must prepare a thesis proposal and have it approved by their thesis committee and the CPTS Program Directors using the Approval of Thesis Proposal Form (https://www.phs.wakehealth.edu/docs/cpts/APPROVAL%20OF%20THESIS%20PROPOSAL%20FORM.pdf). The proposal needs to be submitted prior to pursuing any statistical analyses. The thesis proposal consists of three elements:

1. A literature review demonstrating the student has sufficient background knowledge to pursue the proposed work and can use this knowledge to craft a rationale for the proposed specific aims. The literature review also will form the basis for the first chapter of the written thesis.

2. A statement of specific aims that address an important question in clinical or population translational sciences and should be feasible within the scope of a thesis. This generally means a single outcome and single multivariable model approach, with one to three predictors of interest and several co-variables that may be confounders or effect modifiers. Multiple outcomes and model types fall outside the scope of a thesis.

3. A set of mock (“skeleton”) tables and/or figures that will serve as the basis for the analysis and presentation of results. A brief written description of the proposed analysis may also be included.

There are no page requirements or limitations for the thesis proposal. A typical proposal includes 10 to 15 double-spaced pages of literature review; 1 to 2 pages outlining the specific aims; and approximately 5 to 10 pages of mock tables.

The student should forward their proposal to the CPTS Program immediately after receiving approval from their Thesis Committee. The CPTS Program Directors will review the proposal then contact the student and advisor to indicate fully approval, approval with modifications requested, or disapproval with resubmission required. Statistical analyses and other work on the thesis may not proceed until the proposal is approved.

THESIS COMPONENTS

Students are encouraged to approach their thesis as an expanded manuscript, which facilitates submission of their work for publication. This preferred approach requires a three chapter thesis. The first chapter includes a detailed literature review that builds on the literature review presented as part of the thesis proposal. The second chapter takes the form of a single journal article with the student as first author. Although the article must be of sufficient quality for publication in a peer-reviewed journal, submission should only occur after the thesis defense. The third chapter contains ancillary analyses and an expanded discussion that often includes suggestions about future
research to address remaining questions. While students may be encouraged to prepare additional journal articles for publication, they should not be included in full in the thesis.

Students have the option to complete a traditional thesis. This would include four chapters: Introduction, Methods, Results, and Discussion. While the Introduction would be comparable to the first chapter of the preferred approach, the other chapters would be expanded versions of chapters two and three of the preferred approach. Submitting a manuscript from a traditional thesis typically requires substantial additional revisions after completion of the thesis. Therefore, this approach is not encouraged.

Either form of thesis should open with a title page, acknowledgements, table of contents, and abstract. In addition, the final section should include appendices and the student's curriculum vita. Appendices would include any material relevant to the thesis, such as SAS code, questionnaires or a data dictionary.

THESIS FORMAT

The most important principles of thesis formatting are that the document be neat, error free, and consistently and clearly organized. Detailed guidelines are available at [http://graduate.wfu.edu/students/documents/Theses_Dissertations_instructions.pdf](http://graduate.wfu.edu/students/documents/Theses_Dissertations_instructions.pdf). In addition, in the weeks before their defense, each student meets with the Graduate School Registrar to review the format of their thesis. The deadline for this meeting is typically four weeks prior to the end of the semester. Students approaching the thesis as an expanded manuscript should include the chapters mentioned above rather than the traditional chapters mentioned in the Graduate School guidelines. For both thesis approaches, each chapter should include a bibliography at the conclusion of the chapter rather than a cumulative bibliography.

FINAL EXAMINATION AND EXAMINING COMMITTEE

The final examination for the master’s degree is an oral defense of the student’s thesis project. Details on the defense follow below. Students are encouraged to review this information carefully and completely.

The Examining Committee overlaps with but differs from the aforementioned Thesis Committee. The Examining Committee consists of at least three members of the WFU Graduate Faculty. The first member is the Examining Committee Chair, a Graduate Faculty member with relevant topical knowledge who has not worked with the student on their thesis. The remaining Examining Committee members are drawn from the Thesis Committee. When possible, all members of the Thesis Committee are included. If scheduling or other considerations prevent this, the thesis advisor and statistician are given preference and serve on the Examining Committee. The Chair and all other Examining Committee members are appointed by the Dean of the Graduate School upon recommendation by the CPTS Program Directors. The Program Directors may or may not solicit input from the student and/or thesis advisor prior to making Examining
Committee recommendations.

Examining Committee Members should receive the final thesis no less than three weeks prior to the defense. All Committee members must agree that the thesis is of acceptable quality 10 days in advance of the defense. If the Committee has major concerns, the defense will be rescheduled until their concerns are addressed.

The defense opens with an approximately 30 minute presentation of the thesis work by the student. This presentation is an expanded version of a scientific talk at a meeting, allowing the student to demonstrate more in-depth mastery of the background, methods, analysis and conclusions. While only material in the written thesis draft should be presented, it generally is not possible to present the entirety of the thesis. Students are encouraged to seek their faculty advisors’ guidance when preparing this presentation.

The student presentation is followed by about 45 minutes of questioning by the Examining Committee. In addition to questions about the presentation and written thesis, relevant questions from CPTS coursework or clinical or other training can also be posed. The approach to this portion of the defense is highly variable. Sometimes Committees function in a round-robin manner in which each member asks a single question in turn. Others allow each member to ask all their questions then move on to the next member. Some Committees have a more free-flowing approach. The Examining Committee Chair oversees this portion of the defense and is charged with: (1) ensuring the questions are appropriate in terms of content; (2) that the discussion proceeds in a collegial manner; and (3) that all Committee Members have an opportunity to pose questions.

The Committee then deliberates in private after which they meet with the defending student to present their decision. The Examining Committee Chair is responsible for ensuring these deliberations are conducted in a fair and respectful manner. The decision options are: (1) pass with no revisions; (2) pass with minor revisions; (3) pass with major revisions; and (4) fail. Decisions 2 and 3 are by far the most common. The Committee also determines whether revisions require full Committee review or can be approved by the faculty advisor. In the event a student fails, a single re-examination is allowed.

Scheduling of the examination is handled by the CPTS Program Coordinator. Neither students nor any of their advisors may or should attempt to schedule the final examination.

Ideally, the student and the Examining Committee Chair should be physically present at the defense. If a student has left the area prior to their defense, he or she could, at their own cost, make arrangements to return to Winston-Salem for the defense. Alternatively, the student and the committee could arrange for a remote defense, through methods like Skype or Go-to-Meeting. These sorts of venues must be agreed upon in advance by the Examining Committee and the Program Chairs. All costs and arrangements for these sorts of venues are the responsibility of the student.
THESIS COMPLETION POLICY

For the CPTS program, the thesis represents a capstone experience in which students demonstrate the competencies they have acquired during their time in the program. The opportunity to prepare and hopefully publish a first authored manuscript from their thesis also provides students an entrée to their independent research career.

To maximize students’ success with their thesis and retention of competencies developed during the program requires steady progress toward thesis completion, as newly-acquired knowledge and skills may diminish as thesis work is delayed. More importantly, delays prevent students from moving on to more independent work and may limit their ability to compete for extramural career awards and research funding. Finally, providing thesis mentoring represents a substantial and rarely compensated commitment for our faculty; thesis delays can make these commitments unduly burdensome.

Bearing in mind these important considerations, the CPTS program requires that:

1. Students who have completed their coursework must demonstrate progress on their thesis each semester. Progress will be assessed for all thesis students at least twice annually via a brief survey of each student and their thesis advisor. The CPTS Program Directors will review the responses and provide each student and their advisor with confirmation of acceptable progress or notification of concerns. Students with concerns raised will be asked to provide an advisor-endorsed plan for completing their thesis within one year.

2. Students should complete their thesis within one year of finishing their coursework. After two years post-coursework, students must make a formal request of a one-year extensions from the CPTS Program Co-Directors; no more than two one-year extensions are allowed. The relevant form can be found at http://www.phs.wakehealth.edu/public/cptsthesis.cfm. Thus the absolute maximum time allowed to thesis completion will be four years after coursework is completed. The Graduate School policy of six years from matriculation does not apply. Acceptable reasons for an extension will vary and may include delays in acquiring desired data or departure of a thesis mentor from the faculty. Moving on to another training program or permanent position generally will not be considered an acceptable reason for an extension to be granted. Extensions must be requested before the end of the semester in which the student otherwise would be required to complete their thesis.

ADDITIONAL THESIS INFORMATION

Students will be required to attend an orientation to the thesis process at the beginning of the summer session. The CPTS Program has a web page devoted to thesis-related topics at https://www.phs.wakehealth.edu/public/cptsthesis.cfm. This page includes a presentation reviewing the key steps in the thesis process and providing strategic
suggestions, as well as both a broad and more detailed timeline.

**THESIS AND DEFENSE TIMELINES**

Thesis timelines vary widely based on students’ other commitments and thesis proposal. Deadlines established by the Graduate School also shift from semester to semester. Students are thus encouraged to consult regularly with their faculty advisor and the program co-directors to ensure they are on schedule to graduate. The following table outlines key steps and recommended dates linked to the three available graduate dates. The recommended dates should be regarded as minimums; students should allow additional time if possible. This is especially true if you are considering defending your thesis in the summer, targeting an August graduation. Given that your thesis committee needs to attend your defense and that faculty members tend to take time off in the summer, scheduling a defense during the summer is extremely difficult. It would be better all around (including on your nerves) if you defended in the spring or fall, and not when you are rushed and need to get out of Winston-Salem for a new position in another state!

<table>
<thead>
<tr>
<th>Step</th>
<th>Date of Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify faculty advisor</td>
<td>May/June</td>
</tr>
<tr>
<td>Form thesis committee**</td>
<td>June/July</td>
</tr>
<tr>
<td>Obtain approval of thesis proposal**</td>
<td>August</td>
</tr>
<tr>
<td>Admission to degree candidacy**</td>
<td>August</td>
</tr>
<tr>
<td>Commit to timeline</td>
<td>August</td>
</tr>
<tr>
<td>Meet with Advisor to review timeline (meet monthly throughout process)</td>
<td>Early August Late August Early September</td>
</tr>
<tr>
<td>Start data analysis with statistician (meet monthly throughout process)</td>
<td>Early August Early September Early September</td>
</tr>
<tr>
<td>Draft Chapter 1 of thesis</td>
<td>Mid August Mid October Mid October</td>
</tr>
<tr>
<td>Draft Introduction of Paper</td>
<td>Late August Early November Mid December</td>
</tr>
<tr>
<td>Draft Methods Section of Paper</td>
<td>Late August Mid November Mid February</td>
</tr>
<tr>
<td>Draft tables for manuscript/meet with statistician</td>
<td>Late August Mid December Late April</td>
</tr>
<tr>
<td>Meet with advisor and other committee members to:</td>
<td>Early September Early January Early May</td>
</tr>
<tr>
<td>*discuss results</td>
<td></td>
</tr>
<tr>
<td>*determine additional analyses</td>
<td></td>
</tr>
<tr>
<td>*points for discussion/Chapter 3</td>
<td></td>
</tr>
<tr>
<td>*determine readiness to submit intent to graduate form</td>
<td></td>
</tr>
<tr>
<td>Submit Intent to Graduate Form to Graduate School**</td>
<td>Early September Late January Mid May</td>
</tr>
<tr>
<td>– see academic calendar</td>
<td></td>
</tr>
<tr>
<td>Submit complete draft of thesis to thesis committee – allow 2 weeks to review</td>
<td>Mid September Early February Mid May</td>
</tr>
<tr>
<td>Incorporate edits from thesis committee review</td>
<td>Early October Mid February Mid May</td>
</tr>
<tr>
<td>Event</td>
<td>Timeframe</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Meet with thesis advisor and committee members to discuss final thesis</td>
<td>Early October, Late February, Late May</td>
</tr>
<tr>
<td>With support of faculty advisor and thesis committee, request formation of an Examination Committee and scheduling of the oral defense — <strong>no later than 6 weeks prior to last date to defend</strong></td>
<td>Mid October, Early March, Early June</td>
</tr>
<tr>
<td>Meet with registrar to go over formatting of final thesis – see academic calendar</td>
<td>Late October, Late March, Late June</td>
</tr>
<tr>
<td>Submit revised, final draft of thesis to Examination Committee and the CPTS program — <strong>no later than 3 weeks prior to defense date</strong></td>
<td>Early November, Early April, Early July</td>
</tr>
<tr>
<td>Defend thesis at final (oral) examination – see academic calendar</td>
<td>Early December, Late April, Late July</td>
</tr>
<tr>
<td>Submit final thesis and any other required paperwork per requirements of the Graduate School (they provide a checklist when reviewing the draft thesis) – see academic calendar</td>
<td>Early December, Early May, Late July</td>
</tr>
</tbody>
</table>

**Requires form to be submitted**

**ETHICAL CODE OF CONDUCT**

All students are required to adhere to the highest ethical standards in completing their coursework and thesis. Student misconduct will not be tolerated, and may lead to the expulsion of the student from the CPTS Program. Misconduct includes but is not limited to: cheating on exams or other course work; stealing school and/or other students’ property; vandalism; plagiarism and/or failure to cite/credit other professionals for their published work; falsifying data; computer misuse as specified by WFU; or failure to report an Honor Code violation by another student to the WFU Graduate School or CPTS Program Director(s). The Honor Code can be reviewed at [http://graduate.wfu.edu/docs/academics/HonorCode.pdf](http://graduate.wfu.edu/docs/academics/HonorCode.pdf). Suspected ethical misconduct will be referred to the Graduate School Honor Panel for investigation.

**GRADUATE SCHOOL OPPORTUNITIES**

The Graduate School supports a number of events and provides opportunities for professional development. This includes a Graduate Student Association and a research day at which students compete for prizes, as well as travel awards to support presentation of results at professional meetings. Students are encouraged to make full use of these resources.
COURSE DESCRIPTIONS

CPTS 703 and 704, Ethics and Responsibility in CPTS I and II, 1 hour each: This two course sequence covers professional ethics and responsibility for students in the CPTS program. The courses pursue three main objectives: (1) to introduce students to the culture, people and norms of biomedical research in the United States, (2) to identify points of ethical and/or professional conflict and tension in the research world, i.e. moments where incorrect decisions are at risk of being made, (3) to help students develop ethical reasoning skills and a strategy for making appropriate, responsible decisions that are consistent with a high commitment to professionalism and social responsibility. Students will also be required to complete the Collaborative Institutional Training Initiative (CITI) Human Research On-Line Curriculum as part of this course.

CPTS 720, Epidemiology, 4 hours: This course will provide students with an introductory-level foundation in the history, concepts, and methods of epidemiology. Topics include measurement of prevalence, incidence, association, and sensitivity/specificity. Study designs, threats to validly, effect measure modification and causality are discussed. The course culminates in a project designed to guide the student through the process of formulating a research question, reviewing the literature, and identifying an appropriate study design to address the research question.

CPTS 730, Introduction to Statistics, 4 hours: The course is an introduction to statistical concepts and basic methodologies that are prevalent in biomedical literature. It includes discussion of such topics as descriptive statistics, probability, sampling distributions, hypothesis testing, simple linear regression, correlation, one-way analysis of variance, categorical data analysis, survival analysis, sample size and power analysis, and nonparametric methods.

CPTS 732, Applied Linear Models, 4 hours: The topics of the course include statistical concepts and basic methodologies related to the general linear model and its extensions. The basic statistical procedures discussed in the course include simple and multiple linear regression, analysis of variance and covariance, logistic regression, and repeated measures analysis. Emphasis is given to proper application and interpretation of statistical methods and results. Prerequisite = CPTS 730, Introduction to Statistics.

CPTS 741, Research Grant Preparation, 3 hours: This course is designed to provide students with the knowledge and skills to develop grant proposals to pursue funding in their areas of interest. Topics covered include: the role of external funding in biomedical research; how to identify public and private sources of funding; required components in any type of grant submission; and human subjects and budgeting considerations. During the course, students develop a research proposal for peer review and critical discussion.

CPTS 742, Clinical Trial Methods, 3 hours: This course will provide students with detailed knowledge of clinical trials methodology from Phase I through Phase IV Trials and beyond. Topics to be covered include: why trials are needed; specification of the trial question(s); basic trial designs; identification of the appropriate study population,
interventions, and response variables (including morbidity, mortality and patient-oriented outcomes); the randomization process; masking; sample size issues; issues in data analysis; recruitment/retention/adherence issues; trial monitoring and interim analyses, assessing/reporting adverse effects; interpreting trial results; meta-analyses; and post-marketing surveillance.

CPTS 748, *Population Methods I*, 2 hours: Successful translation of research into practice takes place in community and health delivery settings, which present unique opportunities and challenges to translational scientists. After an introduction to research in these settings, the course will focus on the development of integrated aims, literature reviews, and conceptual frameworks that provide the necessary foundation for successful community and health delivery translational research. To provide students with the opportunity to expand their ability to develop and communicate research concepts, the course will include numerous in-class activities and several written assignments.

CPTS 749, *Population Methods II*, 4 hours: The opportunities and challenges of translational research in community and health delivery settings require scientists to make informed, strategic choices regarding study designs and methods that will ensure their research questions are answered appropriately. After beginning with an introduction to study designs unique to these settings, the course explores how designs are selected and examines specific application of these designs within the community and health delivery settings. The latter part of the course focuses on measurement, with emphasis on the development of data collection forms and surveys. To provide students with the opportunity to expand their ability to develop and communicate research concepts, the course will include in-class activities plus a presentation and written assignments.

CPTS 750, *Thesis Research*, 3 to 9 hours: Research directed towards the thesis. May be repeated for credit.

CPTS 766, *Individual Study in Clinical and Population Translational Science*, 1 to 4 hours: This offering will provide students with opportunities to pursue advanced topics in their individualized areas of interest with guidance from expert faculty. Potential examples of content areas include, but are not limited to, bioethics, cancer, cardiovascular disease, infectious disease, group randomized trials, qualitative methods, psychometrics, economic analysis, nutritional epidemiology and nutrigenomics, pharmacoepidemiology and pharmacogenomics. Individual studies may also be arranged to provide bench, community or health services research “lab” time for a student interested in translation of knowledge between settings (lab, clinic, healthcare delivery system and community). May be repeated for credit. Permission of instructor required for all students.
PROGRAM LEADERSHIP AND FACULTY

Faculty from the Division of Public Health Sciences teach most of the courses in the CPTS program and also serve on thesis committees. Other Graduate School Faculty may serve as instructors or thesis committee members after consultation with the CPTS program co-directors. Faculty who are not currently appointed to the Graduate School will need to work with the CPTS program co-directors to arrange a permanent or temporary appointment before serving on a thesis committee.

Program Co-Directors

Janet A. Tooze, PhD, MPH (Biostatistical Sciences)
Ronny A. Bell, PhD, MS (Epidemiology and Prevention)

Program Coordinator

Tina Church (Public Health Sciences Administration)